

CLAIMS

What is claimed is:

1. A controlled release, storage stable, pharmaceutical formulation intended for oral administration comprising: an orally active, therapeutic amount of a pharmaceutical composition in controlled release dosage form and an orally active antagonist to said pharmaceutical composition in sufficient quantity to counteract the effects of said pharmaceutical composition, said antagonist in a dosage form that is only orally effective as an antagonist if it is chewed or crushed before oral administration.
2. A pharmaceutical formulation according to claim 1 wherein said pharmaceutical composition is a controlled substance.
- 15 3. A pharmaceutical formulation according to claim 2 wherein said controlled substance is an opioid.
4. A pharmaceutical formulation according to claim 3 wherein said opioid is selected from a group comprising hydrocodone, hydromorphone, oxycodone, morphine sulfate, apomorphine, meperidine or a pharmacologically orally active salt thereof.
- 20 5. A pharmaceutical formulation according to claim 3 wherein said antagonist is selected from a group consisting of said pharmacologically orally active salts of naltrexone and naloxone.
- 25 6. A pharmaceutical formulation according to claim 1 where in said pharmaceutical composition is in a controlled release tablet dosage form.

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7. A pharmaceutical formulation according to claim 1 wherein said pharmaceutical composition is in a controlled release capsule dosage form.

5 8. A pharmaceutical formulation according to claim 7 wherein said pharmaceutical composition is in said controlled release capsule dosage form comprising controlled release pills, granules or pellets.

10 9. A pharmaceutical formulation according to claim 1 wherein said antagonist is coated with a substance that will not release a sufficient quantity of said antagonist to counteract the effects of the pharmaceutical composition when taken orally but will release said sufficient amount if it is chewed or crushed before oral administration.

15 10. A pharmaceutical formulation according to claim 9 wherein said coating of said antagonist is selected from a group consisting of a pharmaceutically accepted plastic, chitin, or wax.

20 11. A method for reducing the potential harm or abuse possible from a controlled release oral dosage form of a pharmaceutical formulation caused by chewing or crushing said pharmaceutical formulation prior to oral administration comprising: combining a therapeutic amount of an orally active pharmaceutical composition in controlled release dosage form and an antagonist to said pharmaceutical composition in sufficient quantity to counteract the effects of said pharmaceutical composition when taken orally, said antagonist being in a dosage form that is only active orally if it is chewed or crushed before oral administration.

25 12. A method according to claim 11, wherein said pharmaceutical formulation is a controlled substance.

13. A method according to claim 12, wherein said controlled substance is an opioid.

14. A method according to claim 13, wherein said opioid is selected from a group consisting of the pharmacologically orally active salts of hydrocodone, hydromorphone, oxycodone, morphine sulfate, apomorphine, and meperidine.

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15. A method according to claim 13 wherein said antagonist is selected from a group consisting of the pharmacologically orally active salts of naltrexone and naloxone.

10 16. A method according to claim 11 wherein said pharmaceutical composition and said antagonist are combined into an orally controlled release tablet dosage form.

15 17. A method according to claim 11 wherein said pharmaceutical composition and said antagonist are combined into an orally controlled release capsule dosage form.

20 18. A composition according to claim 17 wherein said pharmaceutical composition is in said controlled release capsule dosage form comprising controlled release pills, granules or pellets.

25 19. A method according to claim 11 wherein said antagonist is in the dosage form of a pill, granule or pellet which is coated with a substance that will not release an effective amount of said agonist when taken orally but will release an effective amount if said agonist is chewed or crushed before oral administration.

20 20. A method according to claim 19 wherein said coating on said antagonist is selected from a group consisting of a pharmacologically inactive plastic, chitin, or wax.

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